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(2) the anti-diabetic agent is selected from the group consisting of: a sulfonylurea; a biguanide; and an alpha-glucosidase inhibitor.

REMARKS

Claims 30-53 were pending in this application and were rejected in the December 12, 2000, Office action. By this amendment, claims 30, 35, 36, 40, 45, and 49 are amended. After entry of this response, claims 30-53 are pending in the case. No new matter has been added by this amendment.

Applicant thanks Examiner Weddington for the courtesy of a telephone interview with his representative, Dr. Tanya M. Harding, on February 16, 2001. Possible ways to overcome the pending statutory-type double patenting rejection over United States Patent No. 6,153,632, were discussed.

In particular, during the telephone interview Dr. Harding proposed amending the claims to incorporate the phrase "sensitizing cells of a mammal so as to enhance insulin uptake and/or utilization of glucose by the cells," so as to overcome the statutory-type double-patenting rejection. In particular, support for this language can be found at least at page 8, lines 24-27, and lines 31-33, and page 9, lines 1-3, lines 6-9, and lines 13-15. Applicant believes that this language clearly illustrates that the claims of the current application are drawn to a different invention than that claimed in United States Patent No. 6,153,632. Applicant therefore requests that the rejection under 35 U.S.C. §101 be withdrawn.

During the telephone interview, Examiner Weddington indicated that amendment of the independent claims to include this language would overcome the statutory-type double-patenting rejection, and was supported by the specification as it was originally filed.

However, the Examiner further indicated that the proposed claim amendments might lead to an obviousness-type double-patenting rejection over United States Patent No. 6,153,632. The

Examiner suggested that a terminal disclaimer would be sufficient to overcome any such rejection.

Applicant does not concede that the revised claims submitted herewith are obvious over United States Patent No. 6, 153,632. In the interests of accelerating prosecution of the current case, however, Applicant provides herewith a terminal disclaimer, signed by Inventor and Owner Robert B. Rieveley, disclaiming the terminal portion of any patent granted in this application which would extend beyond the expiration date of United States Patent No. 6,153,632.

CONCLUSION

Applicant thanks Examiner Weddington for his helpful suggestions in the telephone interview. Applicant provides herewith both claim amendments as discussed on February 16, 2001, and a terminal disclaimer signed by Inventor Rieveley.

Applicant believes that this response places the application in position for allowance. If any minor issues need to be resolved before a notice of allowance can be issued, the Examiner is requested to telephone the undersigned at the number shown below.

Respectfully submitted,

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Marked-up Version of Amended Claims
Pursuant to 37 C.F.R. §§ 1.121(b)-(c)

30. (Once amended) A method for ~~the treatment of diabetes mellitus~~sensitizing cells of a mammal so as to enhance insulin uptake and/or utilization of glucose by the cells, comprising administering to ~~a person afflicted with diabetes mellitus~~the mammal a therapeutic amount of an insulin sensitizer with a therapeutic amount of a sulfonylurea, a biguanide, or an alpha-glucosidase inhibitor, thereby sensitizing cells of the mammal and enhancing insulin uptake and/or utilization of glucose by the cells.

31. The method of claim 30, comprising administering an insulin sensitizer and a sulfonylurea.

32. The method of claim 30, comprising administering an insulin sensitizer and a biguanide.

33. The method of claim 30, comprising administering an insulin sensitizer and an alpha-glucosidase inhibitor.

34. The method of claim 30, further comprising adding a pharmaceutical carrier to the therapeutically effective amount of the sulfonylurea, the biguanide, or the alpha-glucosidase inhibitor.

35. (Once amended) A composition for sensitizing cells of a mammal so as to enhance insulin uptake and/or utilization of glucose by the cells ~~the treatment of diabetes mellitus~~ comprising:

(a) a therapeutic amount of an insulin sensitizer; and

(b) a therapeutic amount of a sulfonylurea, a biguanide, or an alpha-glucosidase inhibitor.

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36. (Once amended) A composition for sensitizing cells of a mammal so as to enhance insulin uptake and/or utilization of glucose by the cells ~~the treatment of diabetes mellitus in a mammal~~ comprising:

(a) a therapeutically effective amount of a sulfonylurea; and,

(b) a therapeutically effective amount of one or more insulin sensitizers to sensitize the cells of the mammal so as to enhance insulin uptake and/or utilization of glucose by the cells of the mammal thus reducing the therapeutic dose required of the sulfonylurea.

37. The composition of claim 36, further comprising a pharmaceutically acceptable carrier.

38. The composition of claim 36 where the insulin sensitizer is present in the composition in the range of about 10 μg to 10 mg.

39. A composition as claimed in claim 36 wherein the insulin sensitizer is selected from the group consisting of BRL-49653, Pioglitazone HCL, Troglitazone, MC 555, ALRT 268, LGD 1069, Chromic Picolinate, V-411, Vanadyl Sulfate, and Chromic Polynicotinate.

40. (Once amended) A composition for sensitizing cells of a mammal so as to enhance insulin uptake and/or utilization of glucose by the cells~~the treatment of diabetes mellitus in a mammal~~ comprising:

(a) a therapeutically effective amount of a biguanide; and,

(b) a therapeutically effective amount of one or more insulin sensitizers to sensitize the cells of the mammal so as to enhance insulin uptake and/or utilization of glucose by the cells of the mammal thus reducing the therapeutic dose required of the biguanide.

41. The composition of claim 40, further comprising a pharmaceutically acceptable carrier.

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42. The composition of claim 40 where the insulin sensitizer is present in the composition in the range of about 10 μg to 10 mg.

43. A composition as claimed in claim 40 wherein the insulin sensitizer is selected from the group consisting of BRL-49653, Pioglitazone HCL, Troglitazone, MC 555, ALRT 268, LGD 1069, Chromic Picolinate, V-411, Vanadyl Sulfate, and Chromic Polynicotinate.

44. The composition of claim 40 where the biguanide is glucophage.

45. (Once amended) A composition for sensitizing cells of a mammal so as to enhance insulin uptake and/or utilization of glucose by the cells~~the treatment of diabetes mellitus~~ comprising:

(a) a therapeutically effective amount of an alpha-glucosidase inhibitor; and,

(b) a therapeutically effective amount of one or more insulin sensitizers to sensitize the cells of the mammal so as to enhance insulin uptake and/or utilization of glucose by the cells of the mammal thus reducing the therapeutic dose required of the alpha-glucosidase inhibitor.

46. The composition of claim 45, further comprising a pharmaceutically acceptable carrier.

47. The composition of claim 45 where the insulin sensitizer is present in the composition in the range of about 10 μg to 10 mg.

48. A composition as claimed in claim 45 wherein the insulin sensitizer is selected from the group consisting of BRL-49653, Pioglitazone HCL, Troglitazone, MC 555, ALRT 268, LGD 1069, Chromic Picolinate, V-411, Vanadyl Sulfate, and Chromic Polynicotinate.

49. (Once amended) A method for sensitizing cells of a mammal so as to enhance insulin uptake and/or utilization of glucose by the cells~~the treatment of diabetes mellitus~~

comprising administering to ~~a person afflicted with diabetes mellitus~~ the mammal a therapeutic amount of an insulin sensitizer with a therapeutic amount of an orally ingestible anti-diabetic agent, where

(1) the insulin sensitizer is selected from the group consisting of: BRL-49653, Pioglitazone HCL, Troglitazone, MC 555, ALRT 268, LGD 1069, Chromic Picolinate and V-411; and

(2) the anti-diabetic agent is selected from the group consisting of: a sulfonylurea; a biguanide; and an alpha-glucosidase inhibitor.

50. The method of claim 49, wherein the insulin sensitizer is V-411.

51. The method of claim 49, wherein the anti-diabetic agent is a biguanide.

52. The method of claim 49, wherein the anti-diabetic agent is a sulfonylurea.

53. The method of claim 49, wherein the anti-diabetic agent is an alpha-glucosidase inhibitor.

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